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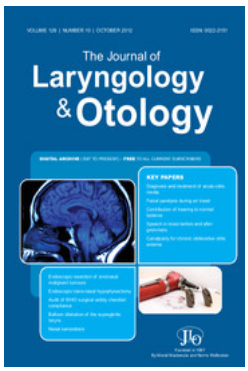


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# Survival times of Provox™ valves

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**Abstract**
This study was performed to assess the survival times of the Provox™ valve in the Manchester area. Thirty-nine patients from four hospitals, representing 81 valve failures, were studied. The effects of the timing of the tracheo-oesophageal puncture, previous radiotherapy, and the presence and timing of cricopharyngeal myotomy on valve life were analysed. Regression analysis using an extension of the Cox model to allow strata showed that the lifetime of the first valve only is adversely affected by previous radiotherapy. The other covariates do not have a statistically significant effect on valve survival. The median valve survival is 4.5 months, (range one to 12 months). A small percentage of valve users with particularly frequent valve failures may require additional support and prolonged anti-fungal therapy.

**Key words: Laryngectomy; Larynx, artificial**

## Introduction

The restoration of speech following total laryngectomy is most commonly achieved by the use of oesophageal speech, an artificial larynx or the creation of a tracheo-oesophageal fistula and valve prosthesis (Garth *et al.*, 1991). The valve prosthesis is generally accepted to be the method of choice in suitable patients, and allows production of a voice of superior quality to that achievable by other methods (Blom *et al*, 1986; Williams and Watson, 1987; Pindzola and Cain, 1988; Hilgers and Schouwenburg, 1990). In Manchester, as in other centres, the Provox™ valve has gained popularity and is now the most commonly used prosthesis. This paper describes some aspects of the experience gained over a period of two years, in 39 patients in whom this valve was used. We were interested to see whether differing pre-operative and operative factors influenced valve survival.

## Patients and methods

The records of all the 42 laryngectomy patients using the Provox™ valve at the time of this study were obtained from five hospitals in the Manchester area. Variations in treatment patterns enabled a comparison of valve survival in terms of radiotherapy and differing surgical techniques in the vocal rehabilitation of laryngectomy patients. In this study, valve failure was defined as salivary leakage through or around the valve, or the inability to effectively produce a voice using the valve, necessitating valve replacement. In patients where a functioning valve was removed at the patient's request, the valve was not considered to have failed, but the data for that patient was censored at that time. Three patients were excluded due to the Provox™ valve being abandoned within one month of insertion. Two were changed to Blom Singer valves and one abandoned due to leakage. The valve failures in the remaining 39 patients were considered in terms of the following parameters: age, sex; radiotherapy treatment; the presence and timing of a cricopharyngeal myotomy; the timing of tracheo-oesophageal puncture and valve insertion; and the intervals between subsequent Provox™ valve replacements. The results were analysed to see if any changes in practice might achieve a more effective and economical use of this prosthesis.

## Results

The valve failure time data is not normally distributed, being positively skewed, with a significant number of longer surviving 'outliers'. This is shown in Figure 1.

### *Age and sex*

The mean age of male patients was 59 years, and of female patients 56.3 years. Overall the mean age at laryngectomy was 58.6 years (Range 42–74). The male to female ratio was 5.5:1.

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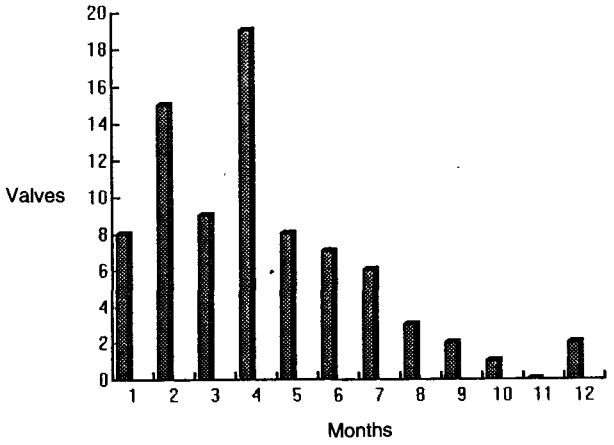


FIG. 1
Valve failures in months.

*Valve lifetimes*

Thirty-nine patients were considered with a total of 81 valve changes. The analysis of the data was complicated by two main factors:

a) On valve failure, a further valve was usually inserted. This process was repeated, up to nine times, in individual patients. We feel that repeated valve failures in an individual are likely to be influenced by factors peculiar to that individual, and cannot be assumed to be independent of each other.

b) The exact lifetime of the last valve inserted is often not known, i.e. the valve hasn't failed at the time of analysis. This is a common feature of analysis of lifetime data known as censoring.

*Statistical methods*

A regression approach to analysis of the data was taken, using an extension of the Cox model to allow strata (Kalbfleisch and Prentice, 1980; Cox and Oakes, 1984). This model has a parametric component representing the covariates of primary interest and a non-parametric component for the actual shape of the underlying lifetime distribution. For the purposes of analysis the 10 per cent of patients who underwent secondary myotomy were grouped with those who had primary myotomy, as they constitute too small a number to evaluate separately.

We wished to assess first failures separately from second failures, separately from third failures, etc. This was achieved by stratifying by failure type (first, second and third), and using only the data on the first three failures in any individual. This approach allows separate quantitative examination of the effects of the covariates on each of the first three failures, and a qualitative comparison of the baseline lifetime distributions.

For failures subsequent to the first failure it is of interest to examine if the length of previous lifetimes has any influence on the lifetime of the current valve. To facilitate this an additional covariate was defined for the second and third valves as being the average lifetime of previous valves for that individual.

The mathematical form of the model is included in appendix 1.

The results showing the parameter estimates and standard errors from fitting this model are shown in Table I. It shows that the only effect that is at all large in relation to its standard error is $Z_1$ (the effect of previous radiotherapy on the first valve lifetime). To test formally if all the other effects may be dropped from the model, we may fit a model with $Z_1$ as the sole covariate and use the likelihood ratio test to compare the two models. This gave a chi-square of 2.90 on 9 degrees of freedom ($p = 0.97$).

The parameter estimate from the reduced model was 0.9007 with a standard error of 0.4131. The effect of this remaining variable was significantly different from zero ($p = 0.03$ likelihood-ratio test). An Arjas plot was constructed and confirmed the assumption of proportional hazards for $Z_1$ (Arjas, 1988).

From the reduced model we have a point estimate of the relative risk of first valve failure in cases with previous radiotherapy compared to no previous radiotherapy of 2.46, with an approximate 95 per cent confidence interval (1.10, 5.53).

Likelihood ratio tests showed that adding age and sex variables to the reduced model had no statistically significant effect (age; $p = 0.15$ and sex; $p = 0.32$). Fom this analysis it appear that the lifetime of the first valve is affected by previous radiotherapy but not by cricopharyngeal myotomy or the timing of the tracheo-oesophageal puncture. Subsequent failures are not significantly affected by any of these features nor by the length of previous valve lifetimes.

The results are summarized in Kaplan-Meier plots, where Figure 2 shows the rate of failure of the first valve in terms of the presence or absence of previous radiotherapy, and Figure 3 shows the failure rate of

TABLE I
PARAMETER ESTIMATES AND STANDARD ERRORS OF THIS MODEL

| Covariate | Variable | Estimate | Standard error |
|---|---|---|---|
| Radiotherapy | $Z_1$ | 0.9373 | 0.4224 |
| | $Z_2$ | −0.3274 | 0.5639 |
| | $Z_3$ | −0.1801 | 0.9240 |
| Cricopharyngeal myotomy | $Z_4$ | 0.0919 | 0.4155 |
| | $Z_5$ | −0.7242 | 0.7056 |
| | $Z_6$ | 0.6634 | 1.2561 |
| Tracheo-oesophageal puncture | $Z_7$ | −0.0953 | 0.4052 |
| | $Z_8$ | −0.2931 | 0.6264 |
| | $Z_9$ | 1.2334 | 1.4083 |
| Previous valves | $Z_{10}$ | 0.0136 | 0.0744 |

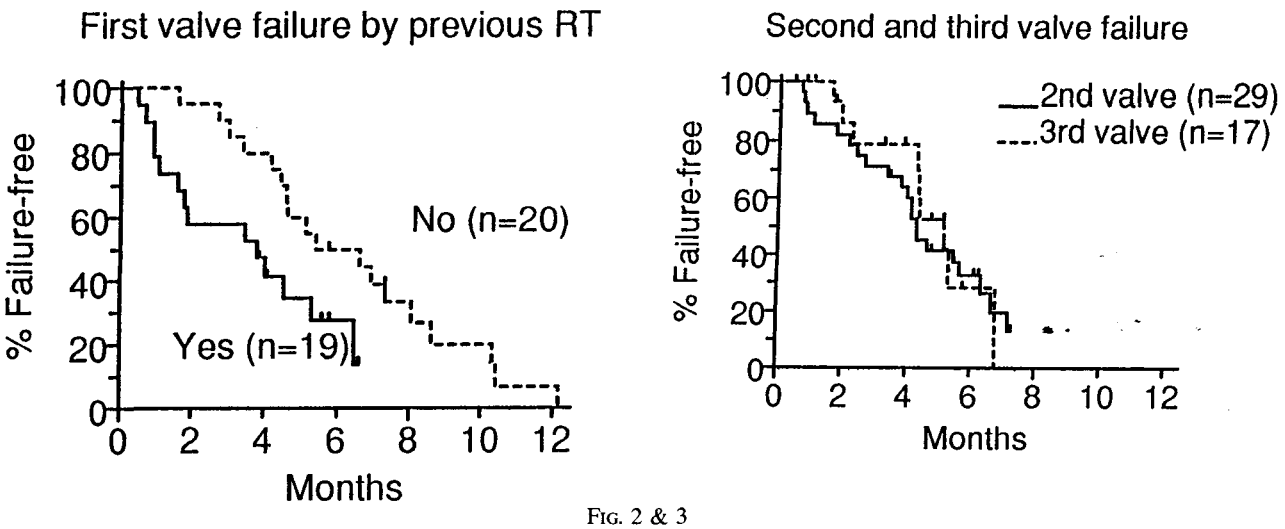


FIG. 2 & 3
Kaplan-Meier plots of valve survival.

the second and third valves (Kaplan and Meier, 1958).

There is a small group of patients (7.7 per cent) with particularly frequent valve failure. They account for 24.7 per cent of valve failures. These patients were more closely scrutinized to see whether they might have medical conditions such as chronic bronchitis or gastric-oesophageal reflux which might possibly adversely affect valve survival. No particular pattern of conditions was identified in this sub-group.

Figure 1 shows the distribution of failed valves, in months. This may reflect bias, as the lifetimes of valves which are still *in situ* at the date of censoring the data are not reflected. These may possibly survive a longer time, shifting the median of this distribution. A more accurate picture is derived from the Kaplan Meier plots in Figures 2 and 3, showing a median valve survival of 4.5 months (137 days) in valves subsequent to the first valve, (where radiotherapy has an influence).

## Discussion

This sample of patients reflect the variable practices of 11 consultants and their junior staff in four centres in and around Manchester. Of this sample, 39 per cent had no cricopharyngeal myotomy, 51 per cent had primary (at laryngectomy) and 10 per cent secondary (delayed) myotomies. Primary tracheo-oesophageal puncture was performed in 55 per cent, secondary tracheo-oesophageal puncture in 45 per cent of patients, while 58 per cent had no previous radiotherapy and 42 per cent previous radiotherapy. There was no significant difference between the valve failure rate in the various centres. The grade of the operating surgeon was not assessed.

All of these patients had a preoperative assessment in conjunction with the respective speech therapy departments, to assess their suitability for fitting the Provox™ valve. This included evaluation of the patients manual dexterity, alcohol intake, motivation, intelligence, and ability to be instructed by the speech therapist. The speech therapists involved with these patients felt that a good quality voice was produced in over 80 per cent, which is comparable to other published results (Yoshida *et al.*, 1989; Hilgers and Schouwenburg, 1990; Hilgers and Balm, 1993). This study does not address the question of the quality of the voice production or patient satisfaction with the prosthesis, but only the lifetime of the valve as reflected by the number of valve changes.

The Provox™ valve has been advocated on the strengths of allowing effortless, fluent speech through a low airflow resistant valve, its optimal self-retaining properties, easy out-patient replacement, and 'long term and predictable device life' (Hilgers and Schouwenburg, 1990). While agreeing that the valve allows production of a superior post-laryngectomy voice, the relative frequency of some patient's valve changes prompted the authors to objectively study the valve life in various centres and assess if this was affected by differing procedures and pre-operative factors.

Eight of the 39 patients (20.5 per cent), with a mean follow-up time of six months (range 4–9 months), had not had the Provox™ valve changed since the initial valve insertion, by the time the data was censored. The analysis cannot only consider valves that have failed, as this disregards those valves *in situ* at the time of censoring, and may create bias against the longer-lasting valves. While considering the quotient of follow-up time and the number of valve replacements may appear to overcome this problem, this assumes that each valve can be considered a separate entity of equal statistical weight. In reality however, there must be individual patient characteristics that influence the valve survival. For example each valve from one patient who has had nine valves in two years will be disproportionately significant compared to those from a patient with only two valve changes in the same period, though the frequent changes may be due to patient factors, such as intractable fungal infestation or poor valve cleaning. We feel that the

modified Cox regression analysis considering only the first three valves in any individual avoids these pitfalls.

Previous radiotherapy significantly accelerates failure of the first valve, but not subsequent valves. We can only speculate that this may be due to poor healing of the tracheo-oesophageal fistula in the tissues compromised by the radiotherapy and that once the fistula is established, this effect is no longer a factor. Hilgers and Balm (1993) have reported that increasing follow-up time has a positive effect on Provox™ valve survival and that patients with hypopharyngeal tumours had shorter valve survival. Interpretation of these results is difficult as mean valve survivals are quoted from data which are not normally distributed. Their overall median Provox™ survival quoted of 141 days is comparable to that shown in our series of 4.5 months (137 days). No patient had a valve surviving longer than 12 months in our series.

By far the most common documented cause of valve failure was leakage of saliva through the valve or valve blockage, both associated with *Candida* sp. infection of the valve. This was almost always a clinical diagnosis and seldom confirmed by microbiological means, though this is being evaluated by a further study. *Candida* colonizes the silicone material causing an increase in airflow resistance and eventual valve failure with the valve either blocking or leaking. Amphotericin-B lozenges decrease candidal colonization and can significantly increase the life of the prosthesis (Mahieu *et al.*, 1986; van Lith-Bijl *et al.*, 1992). Hilgers and Balm (1993) postulate that radiation may alter the pharyngeal microbiological environment and composition of saliva promoting candidal growth. They advocate anti-fungal preparations on the cleaning brush used to clean the valve. Possibly, cleaning of the guide wire with anti-fungal solution during the process of valve change may improve valve survival in those patients where there is obvious candidal presence.

It would seem reasonable to postulate that there are particular 'patient factors' in the 7.7 per cent of our patients in whom valve replacement was particularly frequent, (accounting for 25 per cent of valve failures). These patients should be identified, and targeted to improve valve survival. Possibly those patients in whom valve survival averages less than three months may benefit from prolonged anti-fungal therapy, in combination with reassessment of their competence in cleaning and maintaining the valve, with additional support provided by district nurses or speech therapists. This is the subject of further study.

In three patients (7.7 per cent), leakage around the valve necessitated hospitalization, removal of the valve, and the insertion of a fine-bore naso-gastric tube to allow the fisula to narrow. This corresponds to between 10 per cent and 20 per cent of patients in other series (Hilgers and Schouwenburg, 1990; Hilgers and Balm, 1993). One patient found that his oesophageal voice was so effective that he requested removal of the valve. Other complications associated with the Provox™ valve included the formation of granulations around the valve site and failure in manipulation and use of the valve. Spontaneous closure of the tracheo-oesophageal fistula was unfortunately not the rule in patients who had their valves removed, and surgical closure was required in three cases (7.7 per cent).

Difficulties in changing the valve were not always well documented in the patient's notes, but occurred in a number of patients known to the authors. There was no case of the valve being dislodged into the oesophagus, but in two patients, valve failure was complicated by healing of the oesophageal mucosa, closing the fistula. When the guide wire was inserted through the apparently *in situ* valve this resulted in the creation of a false passage. The guide wire was withdrawn when it did not appear in the pharynx and was found to be blood-stained. Complete healing of the oesophageal mucosa was confirmed by endoscopy and a repeat puncture was required. It is tempting to speculate that this complication occurred because of an inappropriate selection of valve size for the thickness of the tracheo-oesophageal party wall, but in neither patient was this the first valve used, and in both patients the same sized valve (size 8) was subsequently used successfully.

A pharyngeal stricture tends to make changing the valve difficult and in some patients valve changing routinely requires endoscopy and pharyngeal dilatation under a general anaesthetic.

There is no evidence from our data that the presence of a cricopharyngeal myotomy or the timing of the tracheo-oesophageal puncture influence valve survival. This does not exclude the possibility that when larger samples are analysed, these factors may be significant.

Only 51 per cent of this sample had a primary cricopharyngeal myotomy. While this was not shown to have a statistically significant effect on valve survival, there are arguments in favour of routine primary myotomy. An adequate myotomy certainly favourably contributes to voice production by both oesophageal and tracheo-oesophageal speech (Singer and Blom, 1981; Wenig *et al.*, 1989; van Weissenbruch and Albers, 1992; Duguay and Feudo, 1988). Although primary myotomy may produce a hypotonic pharyngo-oesophageal (PE) segment in up to 10 per cent of cases, this can be overcome by pressure applied by the patient's hand, to the neck above the fistula, to narrow the P-E segment during speech (Garth *et al.*, 1991). This complication should be weighed up against the technical difficulties and morbidity of further surgery. Twenty-two per cent of our patients who did not have a primary myotomy, (10 per cent of the total sample), had a secondary myotomy following the demonstration of a hypertonic PE segment on Taub testing(or because of poor voice production with a valve *in situ*. Pharyngeal neurectomy has been proposed as an alternative to cricopharyngeal myotomy but this technique has not gained wide acceptance in Britain (Taub and Bergner, 1973; Singer *et al.*, 1986).

Of our patients, 55 per cent had primary tracheo-oesophageal puncture and valve insertion. This did not appear to affect valve survival. The advantages of primary valve insertion include earlier development of adequate speech and the avoidance of a second surgical episode. We also feel that the creation of the fistula and valve insertion under direct vision is technically easier than as a secondary procedure. Those advocates of delayed valve insertion argue that the valve may promote stomal infection and even mediastinitis, which could substantially prolong the hospital stay. These complications were not evident in the primary valve insertion patients in this series, and there does not appear to be a statistically significant difference between the complication rates in the two approaches in the literature (Trudeau *et al.*, 1986; Maniglia *et al.*, 1989; van Weissenbruch and Albers, 1992). A proportion of our patients who had secondary valve insertion represent those patients who had their laryngectomies before the widespread use of valves for speech rehabilitation, and primary valve insertion is increasingly the trend.

## Conclusions

Previous radiotherapy is likely to adversely affect the life span of the first, but not subsequent valves. The life span of subsequent Provox™ valves, has a distribution median of 4.5 months. There is a small group of patients with particularly rapid valve turnover. These are not identified by pre-operative or operative factors in this study. For economic and logistical reasons, these patients should be identified, (at present empirically), and their ability to maintain the valve reassessed. A long-term course of anti-fungal therapy and additional support from speech therapists or district nurses may be required.

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## Appendix

### Modified Cox Regression Analysis

The mathematical form of the model was as follows:

$\lambda_{ij}(t) = \lambda_{oj}(t)e(\beta_1 Z_{1ij} + \beta_2 Z_{2ij} + \ldots\ldots \beta_{10} Z_{10ij})$

where i indexes individuals (i = 1,2, . . ., 39)

and j indexes the valve (j = 1,2,3)

$\lambda_{ij}(t)$ is the conditional failure rate for the $j^{th}$ valve, on the $i^{th}$ individual, at time t from the insertion of the valve.

$\lambda_{oj}(t)$ is the baseline conditional failure rate for the

$j^{th}$ valve (The actual form of this function is left unspecified).

Type-specific covariates were defined to allow for differing effects of the baseline covariates on each valve failure as follows:

**Radiotherapy (RT)**

$Z_1ij = 0 \quad j \neq 1$ or j=1 and RT = no
$= 1$ j=1 and RT = yes
$Z_2ij = 0 \quad j \neq 2$ or j=2 and RT = no
$= 1$ j=2 and RT = yes
$Z_3ij = 0 \quad j \neq 3$ or j=3 and RT = no
$= 1$ or j=3 and RT = yes

Thus $Z_{1-3}$ represents valve changes 1–3, with or without radiotherapy. Similarly, covariates were defined as cricopharyngeal myotomy ($Z_{4-6}$ representing valve changes 1–3 with or without cricopharyngeal myotomy), and primary and delayed tracheo-oesophageal puncture (where $Z_{7-9}$ represent valve changes 1–3 with respect to this variable). Previous valve lifetime was defined as:

$Z_{10}ij = 0$ j = 1
$Z_{10}ij$ = (average lifetime previous valves)/28 j = 2,3

The results are shown in Table 1 and Figures 2 and 3.